



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0889; FRL-9371-4]

Sulfoxaflor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfoxaflor in or on multiple commodities which are identified and discussed later in this document. DOW AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0889, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0889 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0889, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL-9353-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7777) by DOW AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN, 46268. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide sulfoxaflor, or 1-(6-trifluoromethylpyridin-3-yl)ethyl[(methyl)-oxido- λ 4-sulfanylidene]cyanamide, in or on Crop group 1, subgroup 1A, 1B, Root Vegetables at 0.05 ppm (from carrot, roots at 0.05 ppm; beet, sugar, roots at 0.03 ppm; radish, roots at 0.03 ppm); carrot, juice at 0.15 ppm; beet, sugar, raw sugar at 0.04 ppm; beet, sugar, molasses at 0.3 ppm; beet, sugar, thick juice at 0.15 ppm; beet, sugar, dried pulp at 0.07 ppm; subgroup 1C, 1D, Tuberous and Corm Vegetables at 0.01 ppm; potato at 0.01 ppm; potato, wet peel at 0.02 ppm; potato, chips at 0.02 ppm; potato, dried at 0.02 ppm; potato, granules/flakes at 0.02 ppm; Crop group 2 Leaves of Root and Tuber Vegetables at 4 ppm (from carrot, tops at 4 ppm; beet, sugar, tops at 3 ppm; radish, tops at 0.7 ppm); Crop group 3, subgroup 3-07A Bulb vegetables, Onion, bulb, subgroup at 0.01 ppm (from onion, dry bulb at 0.01 ppm); subgroup 3-07B Bulb Vegetables, Onion, green, subgroup at 0.6 ppm (from onion, green at 0.6 ppm); Crop group 4, subgroup 4A Leafy Vegetables (except Brassica), Leafy

greens, subgroup at 5 ppm (from leafy greens at 1.6 ppm); subgroup 4B Leafy Vegetables (except Brassica), Leafy petioles, subgroup at 1 ppm; (from celery at 1 ppm); Crop group 5, subgroup 5A Brassica Leafy Vegetables, head and stem (except cauliflower) at 1 ppm (from cauliflower at 0.08 ppm; broccoli at 0.45 ppm; cabbage at 1 ppm); subgroup 5B Brassica Leafy Vegetables (from mustard greens at 1.6 ppm); green bean, snap, succulent at 0.7 ppm; beans, dry at 0.25 ppm; Crop group 8 Fruiting Vegetables (except cucurbits, plus okra) at 1.2 ppm (from tomato at 0.45 ppm; pepper, bell and non-bell at 1.2 ppm); tomato, puree at 0.7 ppm; tomato, paste at 1.6 ppm; tomato, catsup at 0.8 ppm; Crop group 9 Cucurbit Vegetables (except squash) at 0.3 ppm (from cucumber at 0.3 ppm; melon at 0.3 ppm); squash at 0.03 ppm; Crop group 10 Citrus Fruits at 0.6 ppm (from orange at 0.6 ppm; lemon at 0.45 ppm; grapefruit at 0.25 ppm); citrus, peel at 1 ppm; citrus, dried pulp, at 0.9 ppm; Crop group 11 Pome Fruits at 0.4 ppm (from apple at 0.3 ppm; pear at 0.4 ppm); apple, dried pomace at 1.3 ppm; Crop Group 12 Stone Fruits (except cherry) at 0.6 ppm (from nectarine, pitted fruit at 0.3 ppm; peach, pitted fruit at 0.6 ppm; plum, pitted fruit at 0.25 ppm); cherry, pitted fruit at 2.5 ppm; cherry, dried cherry at 15 ppm; Crop group 13, subgroup 13-07F Small Fruit Vine Climbing subgroup (except fuzzy kiwifruit) at 1.3 ppm (from grape at 1.3 ppm); grape, raisins at 5 ppm; subgroup 13-07G Low Growing Berry subgroup at 0.6 ppm (from strawberry, fruit at 0.6 ppm); Crop group 14 Tree Nuts (plus pistachio) at 0.02 ppm (from almond at 0.02 ppm; pistachio at 0.02 ppm; pecan at 0.01 ppm); almond, hulls at 4 ppm; Crop group 20, subgroup 20-A Rapeseed subgroup at 0.25 ppm (from canola, seeds at 0.25 ppm); canola, meal at 0.5 ppm; subgroup 20C Cottonseed subgroup at 0.2 ppm (from cotton, seed at 0.2 ppm); cotton, hulls at 0.4 ppm; cotton, gin byproducts at 8 ppm; cotton, aspirated

grain fractions at 4.6 ppm; wheat, grain at 0.07 ppm; wheat, forage at 0.8 ppm; wheat, hay at 1.1 ppm; wheat, straw at 2 ppm; barley, grain at 0.15 ppm; barley hay at 0.8 ppm; barley straw at 1.5 ppm; barley malt sprouts at 0.2 ppm; soybean, seed at 0.2 ppm; soybean hay at 1.8 ppm; soybean, forage at 1.9 ppm; soybean hulls at 0.3 ppm; soybean, meal, toasted at 0.3 ppm; soybean, aspirated grain fractions at 18 ppm. Tolerances of unchanged parent, XDE-208 are also proposed for milk at 0.08 ppm; fat of cattle, goat, horse and sheep at 0.04 ppm; kidney of cattle, goat, horse and sheep at 0.2 ppm; meat of cattle, goat, horse and sheep at 0.1 ppm; meat byproducts of cattle, goat, horse and sheep at 0.25 ppm; fat and meat of hog at 0.01 ppm; meat byproducts of hog at 0.04 ppm; egg at 0.01 ppm; fat and meat of poultry at 0.01 ppm; meat byproduct of poultry at 0.03 ppm. That document referenced a summary of the petition prepared by DOW AgroSciences LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA has increased the proposed tolerances of almond, hulls to 6.0 ppm; barley, grain to 0.4 ppm; barley, hay to 1.0 ppm; barley, straw to 2.0 ppm; beet, sugar, molasses to 0.25 ppm; berry, low growing, subgroup 13-07G to 0.7 ppm; citrus, dried pulp to 3.60 ppm; fruit, citrus, group 10-10 to 0.7 ppm; fruit, pome, group 11-10 to 0.5 ppm; fruit, small, vine climbing, subgroup 13-07F, except fuzzy kiwi fruit to 2.0 ppm; fruit, stone, group 12 to 3.0 ppm; grape, raisin to 6.0 ppm; leafy greens, subgroup 4A to 6.0 ppm; leafy petiole, subgroup 4B to 2.0 ppm; onion, green, subgroup 3-07B to 0.7 ppm; tomato, paste 2.6 ppm; tomato, puree to 1.2 ppm; vegetable, *brassica*, leafy, group 5, except cauliflower to 2.0 ppm;

vegetable, cucurbit, group 9 to 0.4 ppm; vegetable, root and tuber, group 1 to 0.05 ppm; wheat, grain to 0.08 ppm; wheat, forage to 1.0 ppm; wheat, hay to 1.5 ppm; cattle, meat to 0.15 ppm; cattle, fat to 0.1 ppm; cattle, meat byproducts to 0.4 ppm; milk to 0.15 ppm; goat, meat to 0.15 ppm; goat, fat to 0.1 ppm; goat, meat byproducts to 0.4 ppm; horse, meat to 0.15 ppm; horse, fat to 0.1 ppm; horse, meat byproducts to 0.4 ppm; sheep, meat to 0.15 ppm; sheep, fat to 0.1 ppm; and sheep, meat byproducts to 0.4 ppm. EPA has decreased the proposed tolerances of bean, dry seed to 0.2 ppm; bean, succulent to 4.0 ppm; cotton, hulls to 0.35 ppm; cotton, gin byproducts to 6.0 ppm; nuts, tree, group 14 to 0.015 ppm; pistachio to 0.015 ppm; vegetable, fruiting, group 10 to 0.7 ppm; vegetable, leaves of root and tuber, group 2 to 3.0 ppm; hog, meat byproducts to 0.1 ppm; and poultry, meat byproducts to 0.1 ppm. EPA has added the following tolerances: beet, sugar, dried pulp at 0.07 ppm; grain, aspirated fractions at 20.0 ppm; vegetable, legume, foliage, group 7 at 3.0 ppm; and watercress at 6.0 ppm. EPA has not established a tolerance for an individual commodity if that commodity is included in a crop group tolerance. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C)

of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sulfoxaflor including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with sulfoxaflor follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Sulfoxaflor is the first member of a new class of insecticides, the sulfoximines, and is a highly efficacious activator of the nicotinic acetylcholine receptor (nAChR) in insects. Toxicity and mechanistic studies in rats, rabbits, dogs and mice indicate that sulfoxaflor is an activator of the mammalian nAChR as well, but to a much lesser degree and in a species-specific manner. The database of guideline toxicity studies indicates that the nervous system and liver are the target organ systems, resulting in developmental toxicity, hepatotoxicity, and other apical effects.

Developmental/offspring toxicity, manifested as skeletal abnormalities and neonatal deaths, was observed in rats only. The skeletal abnormalities, including forelimb flexure, bent clavicles, and hindlimb rotation, likely resulted from skeletal muscle contraction due to activation of the skeletal muscle nAChR *in utero*. Contraction of the diaphragm, also related to skeletal muscle nAChR activation, prevented normal breathing in neonates and resulted in increased mortality in the reproduction studies. Furthermore, targeted studies indicate that offspring effects are dependent upon *in utero* exposure to sulfoxaflor. The skeletal abnormalities were observed at high doses in the developmental and reproduction studies while decreased neonatal survival was observed at slightly lower levels (e.g., mid- and high-dose animals).

Exposure to sulfoxaflor and its major metabolites resulted in hepatotoxicity in several guideline studies. For example, sulfoxaflor caused liver weight and enzyme changes, hypertrophy, proliferation, and tumors in subchronic and chronic studies. Short-term studies with metabolites resulted in similar liver effects. For sulfoxaflor, hepatotoxicity occurred at lower doses in long-term studies compared to short-term studies.

In addition to the developmental and hepatic effects, treatment with sulfoxaflor resulted in decreased food consumption and body weight as well as changes in the male reproductive system. Decreased body weight, body weight changes, and food consumption were observed during the first few days of several oral studies at the mid- and high-dose levels. As a result of decreased feeding early in the studies, body weights were typically lower in the mid- and high-dose groups compared to the controls, although the differences were not generally statistically significant. Decreased palatability is a

likely contributor to this effect as body weight decreases were often observed at study initiation but were comparable to control animals within several weeks.

Effects in the male reproductive organs were observed in the chronic/carcinogenicity study in rats that included increased testicular and epididymal weights, atrophy of seminiferous tubules, and decreased secretory material in the coagulating glands, prostate, and seminal vesicles. Additionally, there was an increased incidence of interstitial cell (Leydig cell) tumors. The Leydig cell tumors observed after exposure to sulfoxaflor are not considered treatment related due to the lack of dose response, the lack of statistical significance for the combined tumors (unilateral and bilateral), and the high background rates for this tumor type in F344 rats. The primary effects on male reproductive organs are considered secondary to the loss of normal testicular function due to the size of the interstitial cell (Leydig Cell) adenomas. Consequently, the secondary effects to the male reproductive organs are also not considered treatment related.

Clinical indications of neurotoxicity were only observed at high doses in the acute neurotoxicity study in rats. At the highest dose tested, muscle tremors and twitches, convulsions, hindlimb splaying, increased lacrimation and salivation, decreased pupil size and response to touch, gait abnormalities and decreased rectal temperature were observed. Decreased motor activity was also observed in the mid- and high-dose groups. Since the neurotoxicity was observed only at a very high dose and many of the effects are not consistent with the perturbation of the nicotinic receptor system (e.g., salivation, lacrimation, and pupil response), it is unlikely that these effects are due to activation of the nAChR.

Finally, tumors were observed in chronic rat and mouse studies. In rats, significant increases in the incidence of hepatocellular adenomas and combined adenomas and/or carcinomas in the high-dose males were observed when compared to controls. In mice, there were significant increases in hepatocellular adenomas, carcinomas, and combined adenomas and/or carcinomas in high dose males when compared to controls. In female mice, there was an increase in the incidences of carcinomas at the high dose. Although this increase did not reach statistical significance, the incidences exceeded the historical control range for this tumor type was corroborated with the presence of non-neoplastic lesions at this dose. EPA determined that the liver tumors in mice were treatment-related. Using data from several mechanistic studies, EPA also determined that the liver effects in mice and rats are non-linear (threshold) in their mode of action (MoA) and the MoA for the liver tumors is consistent with a constitutive androstane receptor (CAR) mediated, mitogenic mode-of-action. Leydig cell tumors were also observed in the high-dose group of male rats, but it was determined that the tumors were not related to treatment. There was also a significant increase in the incidence of preputial gland tumors in male rats in the high-dose group. Marginal increases were also observed in the low- and mid-dose groups; however, the incident values for these groups were within the range of historical control values. Given that the liver tumors are produced by a non-linear mechanism, the Leydig cell tumors were not treatment-related, and the preputial gland tumors only occurred at the high dose in one sex of one species, EPA concluded that the evidence of potential carcinogenicity was weak and that that quantification of risk using a non-linear approach (i.e., reference dose (RfD)) will adequately account for all chronic toxicity, including any potential

carcinogenic effects, that could result from exposure to sulfoxaflor. The current NOAEL of 5.13 mg/kg/day used for chronic dietary risk assessment is significantly (4x) lower than the dose where tumors were observed ≥ 21.3 mg/kg/day.

In addition, EPA determined there was sufficient evidence to support a developmental mode-of-action (i.e., activation of the nAChR) accounting for the skeletal abnormalities and increased mortality observed in the rat. Furthermore, there was sufficient evidence to support that rats are uniquely sensitive to these developmental effects, informing interspecies uncertainty. Although the database indicates that the developmental effects are unlikely to be relevant to humans, the effects will be considered as relevant to humans unless additional information to the contrary is provided. Data are sufficient to support reducing the interspecies uncertainty factor to 3X for the developmental effects.

Specific information on the studies received and the nature of the adverse effects caused by sulfoxaflor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Sulfoxaflor—New Active Ingredient Human Health Risk Assessment of Uses on Numerous Crops” at pages 14-31 in docket ID number EPA-HQ-OPP-2010-0889.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for

derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>. A summary of the toxicological endpoints for sulfoxaflor used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Sulfoxaflor for Use in Human Health Risk Assessment

| Exposure/Scenario | Point of Departure and Uncertainty/Safety Factors | RfD, PAD, LOC for Risk Assessment | Study and Toxicological Effects |
|---|--|---|--|
| Acute dietary (Females 13-50 years of age) | NOAEL = 1.8 mg/kg/day UF _A = 3x UF _H = 10x FQPA SF = 1x | Acute RfD = 0.06 mg/kg/day aPAD = 0.06 mg/kg/day | Developmental Neurotoxicity Study LOAEL = 7.1 mg/kg/day based on decreased neonatal survival (PND 0-4) |
| Acute dietary (General population including infants and children) | NOAEL = 25 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x | Acute RfD = 0.25 mg/kg/day aPAD = 0.25 mg/kg/day | Acute Neurotoxicity Study LOAEL = 75 mg/kg/day based on decreased motor activity |
| Chronic dietary (All populations) | NOAEL = 5.13 mg/kg/day UF _A = 10x UF _H = 10x | Chronic RfD = 0.05 mg/kg/day | Chronic/Carcinogenicity Study- Rat LOAEL = 21.3 mg/kg/day based on liver effects including increase |

| | | | |
|--|---|--------------------------|--|
| | FQPA SF = 1x | cPAD = 0.05 mg/kg/day | blood cholesterol, liver weight, hypertrophy, fatty change, single cell necrosis and macrophages |
| Dermal short-term (1 to 30 days) and intermediate-term (1 to 6 months) | Dermal (or oral) study NOAEL = 1.8 mg/kg/day (dermal absorption rate = 2.4%) UF _A = 3x UF _H = 10x | LOC for MOE = 30 | Developmental Neurotoxicity Study LOAEL = 7.1 mg/kg/day based on decreased neonatal survival (PND 0-4) |
| Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months) | Inhalation (or oral) study NOAEL = 1.8 mg/kg/day (inhalation absorption rate = 100%) UF _A = 3x UF _H = 10x | LOC for MOE = 30 | Developmental Neurotoxicity Study LOAEL = 7.1 mg/kg/day based on decreased neonatal survival (PND 0-4) |
| Cancer (Oral, dermal, inhalation) | Quantification of risk using a non-linear approach (i.e. reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to sulfoxaflor. | | |

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sulfoxaflor, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from sulfoxaflor in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for sulfoxaflor. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA used maximum residue values from field trials

rather than tolerance-level residue estimates. For crop groups, the residue values were translated from representative crops to the other crops in the group. For processed commodities, empirical processing factors were used for all commodities unless an empirical factor was not available, in which case the DEEM default estimate was used. Residue estimates for livestock were derived using maximum observed residues in the cattle and hen feeding studies. EPA has assumed 100% of crops covered by the registration request are treated with sulfoxaflor.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994-1996 and 1998 CSFII. As to residue levels in food, EPA has made the same refinements as those described for the acute exposure assessment, with two exceptions: (1) Average residue levels from crop field trials were used rather than maximum values and (2) average residues from feeding studies, rather than maximum values, were used to derive residue estimates for livestock commodities. EPA has assumed 100% of crops covered by the registration request are treated with sulfoxaflor.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data is not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A.,

EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to sulfoxaflor. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use PCT information in the dietary assessment for sulfoxaflor. One hundred percent CT was assumed for all food commodities. Maximum residue levels from field trials were used for the acute exposure assessment while average residue levels from field trials were used for the chronic exposure assessment. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for sulfoxaflor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of sulfoxaflor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Two scenarios were modeled, use of sulfoxaflor on non-aquatic row and orchard crops and use of sulfoxaflor on watercress. For the non-aquatic crop scenario, based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of sulfoxaflor for acute exposures are estimated to be 26.4 parts per billion (ppb) for surface water and 69.2 ppb for ground water. For chronic exposures for non-cancer assessments, EDWCs are estimated to be 13.5 ppb for surface water and 69.2 ppb for ground water. For chronic exposures for cancer assessments, EDWCs are estimated to be 9.3 ppb for surface water and 69.2 ppb for ground water.

For the watercress scenario, based on the Tier I Rice Model, the estimated drinking water concentrations (EDWCs) of sulfoxaflor for surface water are estimated to be 91.3 parts per billion (ppb) after one application, 182.5 parts per billion (ppb) after two applications, and 273.8 parts per billion (ppb) after three applications. The 2007 census of agriculture estimates that approximately 680 acres of the U.S. are used for watercress production; thus, this use represents a very small fraction of the potential crop acreage that may be treated with sulfoxaflor. Moreover, the inputs to the Tier 1 rice model are quite conservative, especially with regard to application efficiency (the model assumes that there is no interception of the applied material by the watercress plants) and the 10-cm water column at the time of application (information from watercress growers indicates that watercress fields are drained prior to pesticide applications). Finally, the rice model predicts pesticide concentrations in water in the field and not drinking water *per se* where concentrations are expected to be lower due to dissipation processes such as

degradation, stream flow, and dilution. While the use on watercress may theoretically impact drinking water for a few individuals, EPA does not believe that the EDWCs and residue profiles associated with the watercress use give a representative depiction of the potential exposure profile for any major identifiable subgroup of consumers within the U.S.

EPA has assessed dietary exposure using the EDWCs from both the non-aquatic uses and the watercress use. Dietary risk estimates using both sets of EDWCs are below the Agency's level of concern. For risk characterization purposes, EPA is focusing on the non-aquatic-crop EDWCs because they are more representative of the expected exposure profile for the majority of the population. Furthermore, EPA adjusted the water concentration values to take into account the source of the water (surface water vs. groundwater); the relative amounts of parent sulfoxaflor, X11719474, and X11519540; and the relative liver toxicity of the metabolites as compared to the parent compound (0.3X and 10X for X11719474 and X11519540, respectively). A full discussion of the approach used by EPA is available in Volume 77, No. 189 of the **Federal Register** (77 FR 59561, September 28, 2012). In summary, the three adjusted EDWCs are as follows:

For acute dietary risk assessment of the general population, the groundwater EDWC is greater than the surface water EDWC and was used in the assessment. The residue profile in groundwater is 60.9 ppb X11719474 and 8.3 ppb X11519540 (totaling 69.2 ppb). Parent sulfoxaflor is not expected to occur in groundwater. For this assessment, the regulatory toxicological endpoint is based on neurotoxicity. There is no information to relate the neurotoxicity of the metabolites to that of sulfoxaflor; therefore, no toxicity adjustment was made to the EDWC.

For acute dietary risk assessment of females 13-49, the regulatory endpoint is attributable only to the parent compound (as previously discussed); therefore, the surface water EDWC is the most appropriate EDWC for this assessment even though it is of a lower value than the groundwater EDWC, which reflects metabolites only. The EDWC of 9.4 ppb was used and no toxicological adjustment was made.

For chronic dietary risk assessment, the toxicological endpoint is liver effects, for which it is possible to account for the relative toxicities of X11719474 and X11519540 as compared to sulfoxaflor. The groundwater EDWC is greater than the surface water EDWC. The residue profile in groundwater consists of 60.9 ppb X11719474 and 8.3 ppb X11519540. Adjusting for the relative toxicity results in 18.3 ppb equivalents of X11719474 and 83 ppb X11519540 (totaling 101.3 ppb). The adjusted groundwater EDCW is greater than the surface water EDWC (9.3 ppb) and was, therefore, used to assess the chronic dietary exposure scenario.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Sulfoxaflor is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found sulfoxaflor to share a common

mechanism of toxicity with any other substances, and sulfoxaflor does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sulfoxaflor does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Although there was quantitative susceptibility observed in the developmental neurotoxicity (DNT) study, there is no residual uncertainty because the effects are well characterized, a clear NOAEL was identified, and the endpoints chosen for risk assessment are protective of potential *in utero* and developmental effects. Quantitative susceptibility in the DNT was based on an increased rate of neonatal deaths at a dose where no maternal toxicity was observed. However, the apparent enhanced sensitivity may be due to the limited number of

evaluations conducted in dams in the study rather than a true sensitivity of the young. Qualitative susceptibility was observed in the 2-generation reproduction study since neonatal deaths were observed at the same dose that resulted in hepatotoxicity in parental animals. However, these effects occurred at a higher dose compared to the offspring effects observed in the DNT. Finally, there was no evidence of quantitative or qualitative susceptibility in the developmental studies in the rat or rabbit.

As described in *Section A. Toxicological Profile*, the Agency considers the rat to be uniquely sensitive to these developmental effects. There is sufficient evidence indicating that neonatal death in rats occurs as a result of sulfoxaflor binding to the fetal receptor. Sulfoxaflor does not bind the human fetal receptor in similar manner, precluding developmental effects in humans by this mechanism of toxicity.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for sulfoxaflor is complete.
- ii. The level of concern for neurotoxicity is low because the effects are well characterized, the dose-response curve for these effects is well characterized, and clear NOAELs have been identified.
- iii. Although there is evidence of quantitative susceptibility in the DNT study, based on decreased survival of offspring up to postnatal day 4, the endpoints and doses selected for risk assessment are protective for these effects; further, EPA's degree of concern for human susceptibility is reduced based on the special studies submitted in support of the mode of action.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and either maximum or average residue levels from field trials. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to sulfoxaflor in drinking water. Although some refinements were used in the exposure assessment, the dietary and drinking water assessments will still result in the upper-bound estimates of exposure (see Unit III.C.2).

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to sulfoxaflor will occupy 16% of the aPAD for children 1-2 years old and females 13-49 years old, the population groups receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sulfoxaflor from food and water will utilize 18% of the cPAD for infants, the population group receiving the greatest exposure. There are no residential uses for sulfoxaflor.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, sulfoxaflor is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for sulfoxaflor.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, sulfoxaflor is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for sulfoxaflor.

5. *Aggregate cancer risk for U.S. population.* As described in Unit III.A, EPA has concluded that assessments using a non-linear approach (e.g., a chronic RfD-based

assessment) will adequately account for all chronic toxicity, including carcinogenicity that could result from exposure to sulfoxaflo. Chronic dietary risk estimates are below EPA's level of concern; therefore, cancer risk is also below EPA's level of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sulfoxaflo residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. High performance liquid chromatographic (HPLC) methods with positive-ion electro spray (ESI) tandem mass spectrometry (LC/MS/MS) were developed for data collection and enforcement of sulfoxaflo residues and the two metabolites X11719474 and X11721061. Method 091116 was developed for plant commodities, and Method 091188 was developed for livestock commodities. FDA multiresidue methods are not suitable for analysis of sulfoxaflo; however, data were provided which indicate that the DFG S-19 multiresidue method may provide satisfactory results. The analytical enforcement methodology may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs)

established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established any MRLs for sulfoxaflor.

C. Response to Comments

Two comments were received by email on the notice of filing. One commenter asked for clarification on the proposed tolerance for Subgroup 5B *Brassica* Leafy Vegetables. EPA contacted the registrant and confirmed that the proposed tolerance for this subgroup is 1.6 ppm. The second commenter asked for clarification on the proposed tolerances for Crop Group 1, specifically questioning the discrepancy in proposed tolerances between radish roots and carrot and beets, sugar roots. EPA responded that the tolerances listed in the company's notice of filing are only proposed and not necessarily what the Agency will grant. To cover these commodities, EPA is granting a single tolerance of 0.05 ppm for vegetable, root and tuber, group 1. The comments and EPA responses can be found in the docket.

D. Revisions to Petitioned-For Tolerances

Many of the tolerance levels proposed by the registrant are different from those being established by the EPA. The reason for these differences is that the registrant determined the proposed tolerances using the North American Free-Trade Agreement

tolerance calculator rather than using the Organization for Economic Co-operation and Development (OECD) calculation procedures. In order to maximize global regulatory harmonization, it became EPA policy in April 2011, which was after receipt of the sulfoxaflor submission, to use the OECD calculation procedures to derive tolerance levels. In addition, the registrant proposed tolerances for some crops as both an individual crop and as members of a crop group. EPA has not established a tolerance for an individual commodity if that commodity is included in a crop group tolerance. EPA is not establishing tolerances for cattle, sheep, goat, and horse kidney as proposed, as kidneys are covered under the requested meat byproducts tolerances. Nor is EPA establishing a tolerance for residues in plum, prune, dried as residue levels is adequately addressed by the tolerance listing for the stone fruit crop group raw agricultural commodity. EPA is establishing four tolerances which were not proposed by the petitioner:

Beet, sugar, dried pulp at 0.07 ppm due to the potential for concentration of residues upon production of the dried pulp commodity. The petitioner's evaluation indicates that it did not think a separate tolerance would be necessary but EPA's analysis of the data shows otherwise;

Grain, aspirated fractions at 20 ppm to cover residues in this feed item. The tolerance is necessary to support uses on barley and wheat but a tolerance was not requested, apparently an oversight by the petitioner;

Watercress at 6.0 ppm. The petitioner requested this use but did not provide a requested tolerance level; and

Crop Group 7 (Vegetables, legume, foliage) at 7.0 ppm. The tolerance is necessary to support uses on Crop Group 6 (legume vegetables) but the petitioner only requested tolerances for several individual commodities in Crop Group 7, apparently as an oversight. See Unit II. for specific revisions.

V. Conclusion

Therefore, tolerances are established for residues of sulfoxaflor, 1-(6-trifluoromethylpyridin-3-yl)ethyl[(methyl)-oxido- λ^6 -sulfanylidene]cyanamide, as indicated in Unit II.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 6, 2012.

Steven Bradbury,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.670 is added to subpart C to read as follows:

§180.670 Sulfoxaflor; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide sulfoxaflor, including its metabolites and degradate, in or on the commodities in the table below.

Compliance with the tolerance levels specified below is to be determined by measuring only sulfoxaflor (*N*-[methyloxido[1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]- γ^4 -sulfanylidene]cyanamide).

| Commodity | Parts per million |
|---------------------------------------|-------------------|
| Almond, hulls | 6.0 |
| Barley, grain | 0.40 |
| Barley, hay | 1.0 |
| Barley, straw | 2.0 |
| Bean, dry seed | 0.20 |
| Bean, succulent | 4.0 |
| Beet, sugar, dried pulp | 0.07 |
| Beet, sugar, molasses | 0.25 |
| Berry, low growing, subgroup 13-07G | 0.70 |
| Cattle, fat | 0.10 |
| Cattle, meat | 0.15 |
| Cattle, meat byproducts | 0.40 |
| Cauliflower | 0.08 |
| Citrus, dried pulp | 3.6 |
| Cotton, gin byproducts | 6.0 |
| Cotton, hulls | 0.35 |
| Cottonseed subgroup 20C | 0.20 |
| Fruit, citrus, group 10-10 | 0.70 |
| Fruit, pome, group 11-10 | 0.50 |
| Fruit, small, vine climbing, subgroup | 2.0 |

| | |
|---|-------|
| 13-07F, except fuzzy kiwi fruit | |
| Fruit, stone, group 12 | 3.0 |
| Goat, fat | 0.10 |
| Goat, meat | 0.15 |
| Goat, meat byproducts | 0.40 |
| Grain, aspirated fractions | 20.0 |
| Grape, raisin | 6.0 |
| Hog, fat | 0.01 |
| Hog, meat | 0.01 |
| Hog, meat byproducts | 0.01 |
| Horse, fat | 0.10 |
| Horse, meat | 0.15 |
| Horse, meat byproducts | 0.40 |
| Leafy greens, subgroup 4A | 6.0 |
| Leafy petiole, subgroup 4B | 2.0 |
| Milk | 0.15 |
| Nuts, tree, group 14 | 0.015 |
| Onion, bulb, subgroup 3-07A | 0.01 |
| Onion, green, subgroup 3-07B | 0.70 |
| Pistachio | 0.015 |
| Poultry, eggs | 0.01 |
| Poultry, fat | 0.01 |
| Poultry, meat | 0.01 |
| Poultry, meat byproducts | 0.01 |
| Rapeseed, meal | 0.50 |
| Rapeseed subgroup 20A | 0.40 |
| Sheep, fat | 0.10 |
| Sheep, meat | 0.15 |
| Sheep, meat byproducts | 0.40 |
| Soybean, seed | 0.20 |
| Tomato, paste | 2.60 |
| Tomato, puree | 1.20 |
| Vegetable, <i>brassica</i> , leafy, group 5, except cauliflower | 2.0 |
| Vegetable, cucurbit, group 9 | 0.40 |
| Vegetable, fruiting, group 8-10 | 0.70 |
| Vegetable, leaves of root and tuber, group 2 | 3.0 |
| Vegetable, legume, group 7 | 3.0 |
| Vegetable, root and tuber, group 1 | 0.05 |
| Watercress | 6.0 |
| Wheat, forage | 1.0 |
| Wheat, grain | 0.08 |
| Wheat, hay | 1.5 |
| Wheat, straw | 2.0 |

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent registrations.* [Reserved]

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